REMARKS

This is a response to the Office Action dated July 9, 2004.

I. SUMMARY OF OFFICE ACTION

In the Office Action, the Examiner objected to Claim 14 based on a contention that "to" should be inserted after "proportional."

Claims 1-16 were rejected under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention based on a contention that "and" should be inserted after "electrode" in Claim 1, line 14, "being" should be placed after "electrodes" in Claim 1, last line, the last element in a Markush group should be preceded with "and" in Claims 1-5 and 8, and the dependent claims have the same deficiencies as the base and intervening claims indicated above.

Claims 1-3, 5-7, 9-13 and 16 were rejected under 35 USC § 102(b) as being anticipated by Kulys et al. ("Glucose biosensor based on the incorporation of Meldola Blue and glucose oxidase within carbon paste," *Analytica Chimica Acta* 288 (1994) 193-196). Claims 1-3, 5, 6, 10, 11 and 16 were rejected under 35 USC § 102(b) as being anticipated by Nishizawa et al. ("Penicillan Sensor Based on a Microarray Electrode Coasted with pH-Responsive Polypyrrole," *Anal. Chem.* 1992, 664, 2642-2644). Claims 1-3, 6-12 and 16 were also rejected under 35 USC § 102(b) as being anticipated by Castanon et al. ("Biosensors & Bioelectronics vol. 12, no. 6, pp. 511-520).

Additionally, Claim 4 was rejected under 35 USC § 103(a) as being unpatentable over Nishizawa et al. based on a contention that it would have been obvious to use other enzymes such as those listed in Claim 4.

Importantly, the Examiner stated that Claims 14 and 15 would be allowable if rewritten to overcome the rejections under 35 USC § 112, second paragraph discussed above and to include all of the limitations of the base claim and any intervening claims.

II. APPLICANTS'S RESPONSE

A. Claims 14 and 15

In the Office Action, the Examiner indicated that Claims 14 and 15 would be allowable if amended to overcome the rejections under 35 USC § 112, second paragraph

listed in the Office Action and to include all limitations of its base claim and any intervening claims. Applicants have amended Claims 14 and 15 to overcome the rejections under 35 USC § 112, second paragraph discussed in the Office Action and to include the limitations of its base Claim 1 and intervening Claim 11. Hence, Applicants respectfully submit that amended Claims 14 and 15 are in condition for allowance.

B. Claim 1-13 and 16

In the Office Action, the Examiner rejected Claim 1 under 35 USC § 102(b) as being anticipated by Kulys et al., Nishizawa et al. and Castanon et al. In response, Applicants have amended Claim 1 to specifically exclude oxidoreductase enzymes from its scope. In particular, amended Claim 1 recites that the biocatalyst is one that does not belong to the group of oxidoreductase enzymes. Also, Applicants respectfully submit that Kulys et al. and Catanon et al. do not disclose a biocatalyst not belonging to the group of oxidoreductase enzymes that produces a pH change by its interaction with an analyte as recited in Claim 1. The biocatalyst of Kulys et al. and Catanon et al. are a glucose oxidase and alcohol dehydrogenase, both belonging to the group of oxidoreductase enzymes. Hence, Applicants respectfully submit that Claim 1 is novel with respect to Kulys et al. and Catanon et al.

Additionally, the invention recited in Claim 1 is also novel with respect to Nishizawa et al. based on a contention that Claim 1 recites an ammeter but Nishizawa et al. does not disclose an ammeter. The Examiner indicated that an ammeter is implied by Figure 2 of Nishizawa but Applicants respectfully submit that Figure 2 does not imply the ammeter. Ammeters measure electrical current intensity – Amperes - flowing through a material and do not measure an electrical property of the material - conductivity. In contrast, the device which is implied by Figure 2 of Nishizawa measures an electrical property of the material, namely, conductivity based on a view that the Y axis of Figure 2 is identified by I_D – a unit of conductivity. As such, the device implied by Figure 2 is a conductometer and not an ammeter. Hence, Claim 1 is believed to be novel with respect to Nishizawa et al.

Furthermore, Applicants respectfully direct the Examiner's attention to MPEP § 2143.01 which recites "if the proposed modification or combination of the prior art would change the principal of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious." *In re Ratti*, 270

F.2d 810, 123 USPQ 349 (CCPA 1959). In the present case, there is no motivation to modify the teachings of Kulys et al., Catanon et al. and Nishizawa et al. to make the invention recited in Claim 1 based on a view that to do so would change the principal of operation of the teachings disclosed in Kulys et al., Catanon et al. and Nishizawa et al.

In the biosensors taught in Kulys et al. and Catanon et al., the analyte is first subjected to oxidation or reduction. The electrons involved in this reaction are transferred from the analyte to the working electrode. The current movement involved in this transfer is then measured by the ammeter. These biosensors operate via an easily oxidizable/reducible compound, whose function is to make possible the shuttling of electrons from the analyte to the working electrode. The role of the compound is to "receive and pass" the electrons on their way from the biocatalyst to the working electrode and to lower the thermodynamic barriers opposing this process. *Cf.* Kulys et al. at 195.

In Nishizawa, the compound is represented by a polypyrrole film: this film is subjected to a suitable potential and a base conductivity is measured. In particular, after the analyte-biocatalyst interaction, a pH change is generated and the pH change modifies the conductivity of the film. Similar to Kulys et al. and Castanon et al., the compound works merely as an inert support, receiving and passing a flux of electrons originated from outside the film.

The biosensor as recited in Claim 1 operates in a different manner. In particular, the variation of pH changes the redox property of the compound, i.e., it modifies the equilibrium between the oxidized and reduced form of the compound. This modification of the equilibrium produces an electron current originating from the compound which is proportional to the analyte concentration and is monitored amperometrically. In sum, the compound as recited in Claim 1 does not merely receive and pass electrons but originates the electron current being measured. This novel and non-obvious approach results in biosensors which are not restricted to oxidisable analytes and improves sensitivity and linearity. Hence, Applicants' respectfully submit that Claim 1 is believed to be in condition for allowance. The dependent claims of Claim 1, namely, Claims 2-13, 16 and 17 are also believed to be in condition for allowance for containing additional patentable subject matter and for being dependent on Claim 1 which is also believed to be in condition for allowance.

III. CONCLUSION

For the foregoing reasons, Applicants respectfully submit that Claims 1-17 are in condition for allowance. Applicants respectfully submit that all the stated grounds of objection and rejections have been overcome. Accordingly, an early Notice of Allowance is respectfully requested. Should the Examiner have any suggestions for expediting allowance of the application, the Examiner is invited to contact Applicants' representative at the number listed below.

If any additional fee is required, please charge Deposit Account Number 19-4330.

Respectfully submitted,

Date: 1/6/05 By: _____

Kit M. Stetina
Registration No. 29,445
STETINA BRUNDA GARRED & BRUCKER
75 Enterprise, Suite 250
Aliso Viejo, California 92656
Telephone: (949) 855-1246
Fax: (949) 855-6371

Customer No.: 007663

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